UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SOHEI KANNO, EIICHIRO KIMURA, KAZUHIKO MATSUI and TSUYOSHI NAKAMATSU

Appeal No. 2006-0327
Application No. 09/868,338

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 7, 15 and 16,[1] which are reproduced below:

7. An isolated DNA comprising the nucleotide sequence of nucleotide number 1117 to 1725 of SEQ ID NO: 7.

15. An isolated protein encoded by the DNA of claim 7.

16. An isolated protein of claim 15, wherein said protein has the amino acid sequence of SEQ ID NO: 9.

[1] Claims 1-4, 7 and 9-16 are pending, claims 1-4 and 9-14 stand withdrawn from consideration as being drawn to a non-elected invention. See Appeal Brief, page 3.

Claims 7, 15 and 16 stand rejected under 35 U.S.C. § 101, on the grounds that the claimed invention lacks a patentable utility. In addition, the claims stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that since the claimed invention lacks patentable utility, one skilled in the art would not know how to use the invention. After careful review of the record and consideration of the issues before us, we affirm both rejections.

BACKGROUND

According to the specification, there are several ways in which amino acids and ions may be transported through cell membranes, with the ATP-binding cassette superfamily (ABC transporters) being one such mechanism. See id. at 1. The function of the ABC transporters "is primarily uptake of substances into a cell, but the ATP-binding cassette is considered to also participate in excretion of substances to some extent." Id.

In the process of cloning a gene for an enzyme involved in one of the L-glutamic acid biosynthetic pathways, the inventors "accidentally found that a DNA fragment containing a gene coding for GOGAT (*gltBD*) contained a gene coding for an ABC transporter considered to be involved in transport of amino acids, and thus accomplished the present invention." Id. at 2-3. Thus, "[t]he present invention relates to a novel ABC transporter and a gene coding for a protein that is a constituent of the ABC transporter. The gene can be utilized for breeding of a microorganism showing modified transport of amino acids across a cell membrane and so forth." Id. at 1.

The specification explains how the DNA of the invention was found and may be obtained, see id. at 4-7; see also page 16, Example 1, and that the sequences were compared to known sequences for homology, where it was found that they exhibited homology to ABC transporters responsible for transport of amino acids, see id. at 7.

DISCUSSION

Claims 7, 15 and 16 stand rejected under 35 U.S.C. § 101 "because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility." Examiner's Answer, page 3.

The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The United States Court of Appeals for the Federal Circuit, our reviewing court, recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. See id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a

substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." Id. Thus, "'[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities.'" Id. at 1372, 76 USPQ2d at 1230 (quoting MPEP § 2107.01, 8th Ed. 2001, rev. May 2004).

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any ESTs for that matter, could possibly achieve, but none for which they could have been used in the real world." Id. at 1373, 76 USPQ at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the . . . ways disclosed in the . . . application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

In this case, the examiner notes that "the specification states that the claimed invention is, 'a novel ABC transporter and gene coding for a protein that is a constituent of the ABC transporter and the gene can be utilized for breeding of microorganisms showing modified transport of amino acids across a cell membrane and so forth.'" Office Action mailed January 14, 2004, page 5. The examiner rejected that utility, however, citing Higgins,[2] on the basis that "there is not a 'well established utility' for claimed ABC transporter because the amino acids transported have not been disclosed and ABC transporters comprise a family of functionally and pharmacologically diverse compound transporters with diverse effects." Id.

Appellants have used homology "to form the basis for the utility for the claimed ABC protein/DNA," but the examiner contends that "[t]here is no disclosure in the art that proteins which have the homology disclosed in the specification are 'sufficiently similar' and have the same function or transport the same compounds." Id. at 6. The examiner asserts further "[b]ased on the diversity of activity, functionality and ligand specificity of the ABC transporter family further experimentation is required to attach a specific function to the claimed ABC transporter." Id. at 7. The examiner thus concludes:

> Therefore the claimed ABC protein/DNA, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed polypeptide/DNA.

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[2] Higgins, "ABC Transporters: From Microorganisms to Man," Ann. Rev. Cell Biol., Vol. 8, pp. 67-113 (1992). Note that Higgins is reference AAA on the Information Disclosure Statement dated September 24, 2001.

> This further characterization, however, is part of the act of invention, and until it has been undertaken, Applicants' claimed invention is incomplete.

Id. at 8.

We agree with the examiner that the specification fails to disclose a utility for the claimed ABC transporter protein and the DNA that encodes said protein that satisfies the requirements of 35 U.S.C. § 101, and the rejection is affirmed.

Appellants argue that the examiner has erroneously argued that the asserted utility is the treatment of unspecified, undisclosed diseases or conditions. See Appeal Brief, page 5. According to appellants, "[t]he asserted utility of the claimed gene and protein of the present invention is that they are useful for breeding of a microorganism for the purpose of modifying transport of L-amino acids across a cell membrane." Id. at 5-6. As can be seen above, however, the examiner recognized that a utility disclosed by the specification for the claimed DNA/polypeptide is the breeding of microorganisms showing modified transport of amino acids across a cell membrane, but argues that over 50 ABC transporters are known and their specificities are varied and diverse. See Office Action mailed January 14, 2004, page 5.

Appellants assert in response that that assertion actually "bolsters the argument that the invention has a specific and substantial utility, "[and] since appellants have shown that the novel gene and protein claimed is an ABC transporter, and this class of compounds is well-established class of compounds with a specific function in the cell machinery, i.e. that of facilitating ligands into

and out of the cell." Appeal Brief, page 6. Appellants assert that the examiner has failed "to establish reasonable doubt of the objective truth . . . [of the asserted utility], and the examiner has provided absolutely no evidence to support his otherwise bald assertions." Id. at 7.

Appellants argue further that they have established that the claimed gene/protein is a member of the ABC transporter family by providing a FASTA search of the protein of SEQ ID NO: 9, and the only matches that were found to have significant homology are ABC transporters. See id. As an ABC transporter, appellants contend, the claimed gene/protein has several utilities: the transport of L-amino acids across the cell membrane, for secreting L-amino acids out of the cell, and importing L-amino acids into the cell, citing Zhang[3] to demonstrate the known usefulness of ABC transporters as L-amino acid transporters, as well as Kimura[4] and Vrlijc,[5] to demonstrate that production of an L-amino acid can be affected by disrupting a gene which encodes an L-amino acid uptake protein, or that amplifying a gene involved in L-amino acid transport can enhance the production of an L-amino acid. See id. at 7-8. Thus, according to appellants, "[a]ny person of ordinary skill in the art would recognize this utility as useful and 'in currently available form' and not merely an object of further 'use-testing.'" Id. at 7.

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[3] Zhang et al. (Zhang), "A transporter of Escherichia Coli specific for L- and D-methionine is the prototype for a new family within the ABC superfamily," Arch. Microbiol., Vol. 180, pp. 88-100, (2003).

[4] Kimura et al. (Kimura), EP 1038970, published September 27, 2000.

[5] Vrlijc et al. (Vrlijc), AU 199719218, published July 17, 1997.

Appellants' arguments are not found to be convincing. The issue is not whether the claimed gene/protein is an ABC transporter protein, but whether that is enough to impart a specific and substantial utility as defined by the Fisher court.

As noted by the examiner, Higgins teaches that there is a great diversity in function in the ABC transporter superfamily. See Examiner's Answer, pages 4-6; see also Final Office Action, mailed October 6, 2004, pages 4-6.[6]

Higgens teaches:

- The ABC transporter superfamily is the largest and most diverse of the families of membrane transport systems, with the designation of ABC transporter recognizing a highly conserved ATP-binding cassette, which is the most characteristic feature of the superfamily. Id. at 68.

- Each ABC transporter is relatively specific for a given substrate, but the variety of substrates handled is enormous, including amino acids, sugars, inorganic ions, polysaccharides, peptides and proteins. The mechanism by which such diversity is achieved, while each transporter retains a high degree of selectivity for its own particular substrate, "presents an intriguing problem." Id. at 86.

- Some ABC transporters are uptake (import) systems that accumulate substrate within the cell, while others export substrate from the cell: none has yet been identified that can pump in both directions. Id. at 68.

- It is not yet possible to predict substrate specificity of an ABC transporter, or even the chemical class of substrate, from primary sequence data alone. Id. at 87-88.

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[6] We acknowledge that the referenced arguments are in the "Response to Argument" section, and not in the rejection proper. The rejection, however, references Higgins, and as the examiner presented them in the Final Office Action, we deem them do have been adequately before appellants.

All that is disclosed by the specification for the claimed gene/protein is the primary sequence data. As noted above by Higgins, however, the ordinary artisan would not be able to determine whether the claimed gene/protein is an importer or exporter, the L-amino acid being transported, or even that the claimed gene/protein is an L-amino acid transporter, from that sequence data alone. Thus, the only way that the claimed gene/protein could be used in the asserted utility of breeding microorganisms for the purpose of modifying transport of L-amino acids across a cell membrane, is to undertake further research to determine if the claimed gene/protein is an importer or exporter, which class of substrate it is specific for, and if it is a L-amino acid transporter, which L-amino acid it transports. Thus, the claimed gene/protein does not have a specific and substantial utility as it does not have a disclosed utility that has a significant and presently available benefit to the public.

Appellants' citation of Zhang, Kimura and Vrlijc, also does not demonstrate that the claimed gene/protein has a patentable utility. Zhang discloses an ABC transporter that transports L- and D-methionine. See id., abstract. Kimura is drawn to a method of producing L-glutamic acid, wherein an L-glutamic uptake system is deleted or decreased in the coryneform bacterium, see id., abstract, while Vrlijc is drawn to the use of a lysine export protein, see id. at 10-11. We are not stating that ABC transporters do not have a patentable utility if the substrate specificity is known, but that is not the case here. Given the diversity of the family and the diversity of substrates for the ABC

transporters, the claimed gene/protein, which does not have a known substrate specificity, does not have a specific and substantial utility as defined by the Fisher court.

Moreover, in response to the examiner's assertion that the claimed gene/protein has not been identified as an importer or exporter, appellants contend that "there are multiple instances whereby appellants assert in their specification that the transporter is effective for exporting of L-amino acids for use in bacterial fermentative production of said L-amino acids," and that they "clearly state that the asserted utility of the novel ABC transporter gene/protein is for transporting L-amino acids in/out of the cell." Appeal Brief, page 9.

Appellants' arguments are again not found to be convincing. As noted above, all that has been disclosed for the claimed gene/protein is the primary sequence data. And as also noted above, as taught by Higgins, one cannot determine substrate class, substrate specificity, or whether the transporter is an importer or an exporter, from sequence data alone. Thus, the examiner is relying on evidence that has not been adequately rebutted by appellants, demonstrating that that one of ordinary skill in the art would reasonably doubt the asserted utility.

Claims 7, 15 and 16 also stand rejected under 35 U.S.C. 112, first paragraph, on the grounds that "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to

use the claimed invention." Examiner's Answer, page 3. To the extent that the enablement rejection is a corollary of the examiner's finding of lack of utility, we agree, and the rejection is affirmed. See Fisher, 421 F.3d at 1378, 76 USPQ2d at 1235 ("If the application fails as a matter of law to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.").

CONCLUSION

Because we find that the specification does not disclose a specific and substantial utility, we affirm the rejection of claims 7, 15, and 16 under 35 U.S.C. § 101. Because we affirm that rejection, we also affirm the rejection of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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